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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,327	05/15/2002	Jay M Meythaler	UAB-15102/22	3596

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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,327	MEYTHALER ET AL.	
	Examiner	Art Unit	
	Gregory W Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7 and 29-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7 and 29-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the remarks and amendments filed July 29, 2004. Claims 1, 29, 35, and 36 have been amended. Claims 8-28 have been cancelled. Claims 1, 4-7 and 29-41 are pending and examined herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 29, 36, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "analog" is indefinite. The term "analog" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

invention. It is unclear what compounds are intended to be encompassed by the term "analog". "Analog" is defined as something that is similar to something else. Does that mean that the claim is intended to encompass all structures even remotely similar to all known NSAIDs? Do these other structures have to have non-steroidal anti-inflammatory activity?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-7, 29, 30, 32-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grilli et al. (WO 98/20864) in view of Eisenbach-Schwartz et al. (USPN 6126939).

Grilli et al. teaches the treatment of Alzheimer's disease through the use of NSAIDs (Abstract). Sodium salicylate and salicylamide are specifically taught as NSAIDs useful in the invention disclosed therein (p 3). Neuronal damages (i.e. neurotrauma or neuronal injury) related to Alzheimer's disease are specifically taught as treatable by the NSAIDs disclosed therein (p 6). Generally, cranial and spinal traumas are also taught to be treatable by the methods disclosed (p 6). Grilli et al. lacks a specific teaching of the claimed mode of administration.

Eisenbach-Schwartz et al. teaches a pharmaceutical composition with non-steroidal anti-inflammatory activity for the treatment of Alzheimer's disease which may be administered to the central nervous system by intraventricular or intrathecal injection wherein the injection may be facilitated by a catheter (col. 4, lines 51-56; col. 6, lines 16-25; col. 13, lines 46-63).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the composition of Grilli et al. for the treatment of Alzheimer's disease and any neuronal damage associated therewith because (1) Grilli et al. teaches the administration of the composition for said treatment generally; and (2) Eisenbach-Schwartz et al. teaches the administration of a composition with non-steroidal anti-inflammatory activity useful for the treatment of Alzheimer's disease may be administered by intraventricular or intrathecal injection wherein the injection may be facilitated by a catheter. One would have been motivated to administer the composition of Grilli et al. by intraventricular or intrathecal injection, facilitated by catheter, because of an expectation of success in treating neuronal damage associated with Alzheimer's, as taught by Grilli et al.

It is noted that the recitation of the limitation of "non-inhibitory of platelets" is a recitation of a limitation as to the property of the drug. It is also noted that the recitation provides no information as to how it would limit the structure of the claimed NSAIDs. Accordingly, since Examiner has shown that it is known to administer the same compositions as instantly claimed, the compositions would obviously be non-inhibitory

of platelets. A compound and its properties are inseperable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Claims 4, 31, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grilli et al. and Eisenbach-Schwartz et al. as applied to claims 1, 5-7, 29, 30, 32-36, 38-40 above, and further in view of McGeer et al. (USPN 5192753).

Grilli et al. and Eisenbach-Schwartz et al. apply as disclosed above. It is noted that Grilli et al. also teaches that salicylic acid, acetylsalicylic acid, salicylates, etc. and pharmaceutically acceptable salts of acetylsalicylic acid are useful as NSAIDs in the treatments disclosed therein (p 3). The references lack a teaching of choline magnesium trisalicylate.

McGeer et al. teaches arylcarboxylic acids such as salicylic acid, acetylsalicylic acid, choline magnesium trisalicylate, salicylate, etc. as NSAIDs useful for the treatment of Alzheimer's disease (col. 1, lines 36-65).

It would have been obvious to one of ordinary skill in the art to utilize the specific NSAID choline magnesium trisalicylate in a method of Grilli et al. and Eisenbach-Schwartz et al. because (1) Grilli et al. teaches the use of derivatives of acetylsalicylic acid as NSAIDs useful for the treatment of neuronal damage associated with Alzheimer's disease; (2) Grilli et al. teaches that salicylates and pharmaceutical acceptable salts thereof are useful as NSAIDs in the treatment of neuronal damage associated with Alzheimer's disease; and (3) McGeer et al. teaches that choline magnesium trisalicylate is a salicylate suitable for the treatment of Alzheimer's disease.

One would have been motivated to utilize the specific salicylate choline magnesium trisalicylate because of the expectation of success in treating neuronal damage associated with Alzheimer's disease by administering a derivative of acetylsalicylic acid to a patient in need thereof, as taught by Gilli et al.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-7 and 29-41 have been considered but are moot in view of the new ground(s) of rejection. Examiner's response to the remarks filed, as they pertain to the instant rejections follows.

Applicant argues, "there is a significant difference in degree in both therapeutic effect and invasiveness associated with administration of such drugs by central nervous system catheter according to the claimed invention, as compared to conventional oral, intramuscular or bloodstream administration." This argument is not persuasive for the reasons stated above in the instant rejection, specifically because Eisenbach-Schwartz et al. teaches a pharmaceutical composition with non-steroidal anti-inflammatory activity for the treatment of Alzheimer's disease which may be administered to the central nervous system by intraventricular or intrathecal injection wherein the injection may be facilitated by a catheter. Accordingly, it is Examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention to administer the composition of Gilli et al. by those means.

Applicant further argues, "[t]he non-inhibition of platelets is detailed in the instant specification at page 17, lines 8-13 as being an important attribute of successful

treatment according to the present methodology as contrasted to the prior art." These arguments are not persuasive because the prior art teaches the very same NSAIDs as instantly claimed. A newly discovered property of those same drugs for a treatment taught by the prior art does not render the treatment new.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER